SUBCHAPTER C—DRUGS: GENERAL

PART 200—GENERAL

Subpart A—General Provisions

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Subpart E—Prescription Drug Consumer Price Listing

AUTHORITY: 21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 358, 360e, 371, 374, 375.

SOURCE: 40 FR 13996, Mar. 27, 1975, unless otherwise noted.

Subpart A—General Provisions

§ 200.5 Mailing of important information about drugs.

Manufacturers and distributors of drugs and the Food and Drug Administration occasionally are required to mail important information about drugs to physicians and others responsible for patient care. In the public interest, such mail should be distinctive in appearance so that it will be promptly recognized and read. The Food and Drug Administration will make such mailings in accordance with the specifications set forth in this section. Manufacturers and distributors of drugs are asked to make such mailings as prescribed by this section and not to use the distinctive envelopes for ordinary mail.

(a) Use first class mail and No. 10 white envelopes.

(b) The name and address of the agency or the drug manufacturer or distributor is to appear in the upper left corner of the envelope.

(c) The following statements are to appear in the far left third of the envelope front, in the type and size indicated, centered in a rectangular space approximately 3 inches wide and 2¼ inches high with an approximately ⅜ inch-wide border in the color indicated:

(1) When the information concerns a significant hazard to health, the statement:

IMPORTANT

DRUG

WARNING

The statement shall be in three lines, all capitals, and centered. ''Important'' shall be in 36 point Gothic Bold type. ''Drug'' and ''Warning'' shall be in 36 point Gothic Condensed type. The rectangle's border and the statement therein shall be red.

(2) When the information concerns important changes in drug package labeling, the statement:

IMPORTANT

PRESCRIBING

INFORMATION

The statement shall be in three lines, all capitals, and centered. ''Important'' shall be in 36 point Gothic Bold type. ''Prescribing'' and ''Information'' shall be in 36 point Gothic Condensed type. The rectangle's border and the statement therein shall be blue.

(3) When the information concerns a correction of prescription drug advertising or labeling, the statement:

IMPORTANT

CORRECTION

OF DRUG

INFORMATION

The statement shall be in four lines, all capitals, and centered. ''Important'' shall be in 36 point Gothic Bold type. ''Correction,'' ''Of Drug,'' and ''Information'' shall be in 36 point Gothic Condensed type. The rectangle's border and the statement therein shall be brown.

§ 200.7 Supplying pharmacists with indications and dosage information.

There are presently no regulations under the Federal Food, Drug, and Cosmetic Act that prevent a manufacturer of prescription drugs from sending the pharmacist data he needs on indications and dosage in exercising his important professional function of checking against possible mistakes in a prescription. The Food and Drug Administration believes manufacturers should be encouraged to supply such printed matter to the pharmacist for his professional information. Obviously, such printed matter should not be displayed to prospective purchasers to promote over-the-counter sale of prescription drugs.

§ 200.10 Contract facilities (including consulting laboratories) utilized as extramural facilities by pharmaceutical manufacturers.

(a) Section 704(a) of the Federal Food, Drug, and Cosmetic Act specifically authorizes inspection of consulting laboratories as well as any factory, warehouse, or establishment in which prescription drugs are manufactured, processed, packed, or held.

(b) The Food and Drug Administration is aware that many manufacturers of pharmaceutical products utilize extramural independent contract facilities, such as testing laboratories, contract packers or labelers, and custom grinders, and regards extramural facilities as an extension of the manufacturer's own facility.

(c) The Food and Drug Administration reserves the right to disclose to the pharmaceutical manufacturer, or to the applicant of a new drug application (NDA) or to the sponsor of an Investigational New Drug (IND) Application, any information obtained during the inspection of an extramural facility having a specific bearing on the compliance of the manufacturer's, applicant's, or sponsor's product with the Federal Food, Drug, and Cosmetic Act. The Food and Drug Administration's position is that by the acceptance of such contract work, the extramural facility authorizes such disclosures.

(d) The Food and Drug Administration does not consider results of validation studies of analytical and assay methods and control procedures to be trade secrets that may be withheld from the drug manufacturer by the contracted extramural facility.

[40 FR 13996, Mar. 27, 1975, as amended at 55 FR 11576, Mar. 29, 1990]

§ 200.11 Use of octadecylamine in steam lines of drug establishments.

The Food and Drug Administration will not object to the use of octadecylamine in steam lines where the steam may be used for autoclaving surgical instruments and gauze if the octadecylamine in the steam is not more than 2.4 parts per million.

§ 200.15 Definition of term "insulin".

For the purposes of sections 502(k) and 506 of the act:

(a) The term *insulin* as used therein means the active principle of pancreas which affects the metabolism of carbohydrate in the animal body and which is of value in the treatment of diabetes mellitus.

(b) The following substances, when they are intended for use in the manufacture of insulin-containing drugs that will subsequently be submitted for certification, shall not be considered to be subject to certification as ''drugs composed wholly or partly of insulin'':

(1) Pancreas glands; and

(2) Materials prepared from pancreas glands, such as ''salt cake'' and ''isoelectric precipitate,'' which materials must be subjected to further purification in order to meet the standards of purity established by part 429 of this chapter.